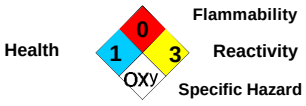
Agrium Material Safety Data Sheet

NFPA Classification	DOT / TDG Pictograms	WHMIS Classification	PROTECTIVE CLOTHING
			

Section I. Chemical Product and Company Identification

PRODUCT NAME/ TRADE NAME	**Ammonium Nitrate, Prilled Fertilizer Grade 34.5-0-0**
SYNONYM	34.5-0-0 Prilled Ammonium Nitrate Fertilizer
CHEMICAL NAME	Ammonium nitrate.
CHEMICAL FAMILY	Nitrate salt. (Oxidizing agent)
CHEMICAL FORMULA	NH_4NO_3
MATERIAL USES	Agricultural industry: Fertilizer. Industrial applications: Manufacture of chemicals. Manufacture of specialty fertilizers.

MSDS NUMBER:	**14082**
REVISION NUMBER	4.6
MSDS prepared by the Environment, Health and Safety Department on:	**March 25, 2003**

24 HR EMERGENCY TELEPHONE NUMBER:

Transportation: 1-800-792-8311
Medical: 1-888-670-8123

MANUFACTURER

Agrium
North American Wholesale
13131 Lake Fraser Drive, S.E.
Calgary, Alberta, Canada
T2J 7E8

SUPPLIER

Agrium
North American Wholesale
13131 Lake Fraser Drive, S.E.
Calgary, Alberta, Canada, T2J 7E8

Agrium U.S. Inc.
Suite 1700, 4582 South Ulster St.
Denver, Colorado, U.S.A., 80237

Section II. Hazardous Ingredients

		Exposure Limits (ACGIH)						
NAME	**CAS #**	**TLV-TWA mg/m³**	**TLV-TWA ppm**	**STEL mg/m³**	**STEL ppm**	**CEIL mg/m³**	**CEIL ppm**	**% by Weight**
Ammonium nitrate	6484-52-2	10						99.8

TOXICOLOGICAL DATA ON INGREDIENTS

Ammonium Nitrate:^

Rat oral LD50: 4500 mg/kg. [Peer Reviewed] [Environment Canada;Tech Info for Problem Spills: Ammonium Nitrate (Draft) p.59 (1981)]
Rat oral LD50: 2217 mg/kg (Rat) [Gigiena i Sanitariya. For English translation, see HYSAAV. (V/O Mezhdunarodnaya Kniga, 113095 Moscow, USSR) V.1- 1936- (52(8),25,1987)]
Huntingdon Research Center Testing Results (3 studies), OECD Guide 401: 2462- 2900 mg/kg (rat oral)
TFI Product Testing Results, OECD Guideline 402: > 5,000 mg/kg acute dermal LD_{50}, rat,
Bacterial reverse mutation assay: negative, with and without metabolic activation, (Salmonella)
Developmental terotogenicity: Not teratogenic to rats. NOAEL >57 mg/kg

Ecotoxicity Values:
Acute fish toxicity: Chinook salmon, rainbow trout, bluegill: 96hr LC_{50} = 420-1360 mg NO_3/L
Acute toxicity to aquatic invertibrates: Daphnia magna EC_{50} = 555mg/L
Acute toxicity to aquatic plants (algae): Scenedesmus quadricauda EC_{50} = 83mg/L
LD50 Aspergillus niger (fungus) 15 mg/l/40 hr (36 deg C). [Peer Reviewed] [Environment Canada; Tech Info]

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Section III. Hazards Identification.

POTENTIAL ACUTE HEALTH EFFECTS	May interfere with the oxygen carrying capacity of the blood if ingested in large quantities or over a prolonged period of time. Persons with anemia, bowel diseases, or infants, are more likely to develop effects. Over-exposure by ingestion is unlikely under normal working conditions. Inhalation of dusts may cause respiratory irritation. This product may irritate eyes and skin upon contact but is unlikely to injure tissue. Symptoms of overexposure may include: Cardiovascular: methemoglobinemia, low blood pressure (hypotension), irregular heart beat (arrhythmia), shock (vasodilation) CNS: headache, dizziness, generalized tingling sensation (parasthesia) Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain Eye: redness and inflammation (conjunctivitis) Skin: bluish discoloration (cyanosis) with profuse sweating following ingestion or irritation and flushed skin following contact with moist skin surfaces.
POTENTIAL CHRONIC HEALTH EFFECTS	**CARCINOGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. **MUTAGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. **TERATOGENIC EFFECTS**: NONE by ACGIH, EPA, IARC, NTP, OSHA. Repeated or prolonged overexposure by ingestion can reduce the oxygen carrying capacity of the blood producing anoxia in infants or individuals with preexisting bowel or blood diseases. Ensure that nitrate containing fertilizers are not applied near wells where contamination may occur. Consult your agronomist regarding the advisability and precautions for use of nitrate fertilizers on fruit or vegetable crops.

Section IV. First Aid Measures

EYE CONTACT	Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Obtain medical attention if irritation persists.
MINOR SKIN CONTACT	May cause skin irritation. Wash contaminated skin with soap and water. Cover dry or irritated skin with a good quality skin lotion. If irritation persists, seek medical attention.
EXTENSIVE SKIN CONTACT	No additional information.
MINOR INHALATION	Inhalation of dust may produce irritation, burning, sneezing and coughing. Long term exposure may cause headache, nausea or weakness. Loosen tight clothing. Allow affected persons to rest in a well ventilated area. Obtain medical attention if irritation persists.
SEVERE INHALATION	In emergency situations use proper respiratory protection to evacuate affected individuals to a safe area as soon as possible. Loosen tight clothing around the person's neck and waist. Oxygen may be administered if breathing is difficult. If the person is not breathing, perform artificial respiration. Obtain immediate medical attention.
SLIGHT INGESTION	If conscious, have person drink several glasses of water or milk and induce vomiting. Never give anything by mouth to an unconscious person. Lower the head so that the vomit will not reenter the mouth and throat. Obtain medical attention.
EXTENSIVE INGESTION	No additional information.

Section V. Fire and Explosion Data

THE PRODUCT IS	Non-flammable.
AUTO-IGNITION TEMPERATURE	Not applicable.
FLASH POINT	Not applicable.
FLAMMABILITY LIMITS	Not applicable.
PRODUCTS OF COMBUSTION	Material will not burn, but thermal decomposition may result in flammable/toxic gases being formed. These products are nitrogen oxides and ammonia (NO, NO_2, NH_3).

Continued on Next Page

FIRE HAZARD IN THE PRESENCE OF VARIOUS SUBSTANCES	Not applicable.
EXPLOSION HAZARD IN THE PRESENCE OF VARIOUS SUBSTANCES	Oxidizer: Material is an oxidizer which may react readily with other materials, especially upon heating. In confinement and in the presence of a strong detonation source, the material can explode when subject to sudden shock, pressure, or high temperature. Avoid temperatures above 210 °C (410 °F) which may cause thermal decomposition or explosion, especially in confined or poorly ventilated spaces. Incompatible with sulfur, chlorides, reducing agents, or other oxidizers. Incompatible with finely powdered metals (cadmium, copper, lead, cobalt, nickel, bismuth, chromium, magnesium, zinc, sodium, potassium and aluminum).
FIRE FIGHTING MEDIA AND INSTRUCTIONS	Oxidizing material. Cool containing vessels with water jet in order to prevent pressure build-up, or explosion. Use flooding quantities of water. Evacuate surrounding area. Material will not burn. Melts and undergoes thermal decomposition at elevated temperatures to release visible clouds of toxic and combustible gases (ammonia, carbon dioxide, and oxides of nitrogen). If fumes or gases may be present, fire fighters should wear self-contained breathing apparatus.
SPECIAL REMARKS ON FIRE HAZARDS	Material supports combustion. Powerful oxidizing agent, supports combustion by liberating oxygen even if smothered. Avoid temperatures above 210°C (410°F) in confined or poorly ventilated spaces. Explosive when exposed to heat or flame under confinement. Avoid pressure build-up. Thermal decomposition or explosion may result. Ventilate to cool and flood with water to stop decomposition reaction. Contain and collect all runoff for treatment. Prevent fire water from reaching water courses or aquifers.
SPECIAL REMARKS ON EXPLOSION HAZARDS	Industry studies have proposed the following rules for blends of ammonium nitrate with phosphate and potassium containing fertilizers: a) Ammonium nitrate fertilizers are reported not to detonate unless the fertilizer contains at least 70% ammonium nitrate, unless ammonium sulfate is present in the blend. Blended ammonium nitrate - ammonium sulfate fertilizers may detonate with as little as 45% ammonium nitrate present. b) It has been reported that it is desirable to keep the ammonium to nitrate ratio above 1.5 in fertilizer blends in order to minimize toxic gas release during "cigar burn" fires. c) "Cigar burn" is considered to be a hazard primarily when the ammonium nitrate content of a blend is between 20-40%. Cigar burn is a rare phenomenon which requires the combustion of a separate combustable material such as sulfur which can cause thermal decomposition of nearby ammonium nitrate.

Section VI. Accidental Release Measures

SMALL SPILL	Use appropriate tools or equipment to place the spilled solid in a suitable container for reuse or disposal.
LARGE SPILL	In the event of a spill, prevent additional discharge of material, if possible to do so without hazard. Prevent spills from entering sewers, watercourses, wells, etc. Product will promote algae growth which may degrade water quality and taste. Notify downstream water users. Nitrate in potable drinking water should be maintained below 10 mg/L. Will dissolve and disperse in water. Put the material into a suitable container for reuse or disposal.

Section VII. Handling and Storage

PRECAUTIONS	Keep away from heat, combustible materials, and reducing agents. Avoid contact with skin and eyes. DO NOT ingest or breathe dust. Take precautions against electrostatic discharges. Keep out of reach of children. Keep away from food, drink and animal feed.
STORAGE	Store in a dry, cool and well ventilated area. Keep away from food, drink and animal feeds. Keep away from combustible materials. Keep away from incompatible materials. Do not blend or store in contact with urea. Dry urea and dry ammonium nitrate will react together to produce a slurry.

Continued on Next Page

Section VIII. Exposure Controls/Personal Protection

ENGINEERING CONTROLS	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, use ventilation to keep exposure to airborne contaminants below the exposure limit.
PERSONAL PROTECTION	The selection of personal protective equipment varies, depending upon conditions of use. Wear appropriate respiratory protection for dust/mist when ventilation is inadequate. A filtering facepiece dust mask is recommended for most applications if respiratory protection is needed. Where skin and eye contact may occur as a result of brief periodic exposures, wear long sleeved clothing, coveralls, chemical resistant gloves, and safety glasses with side shields.
PERSONAL PROTECTION IN CASE OF LARGE RELEASE	No additional information.
EXPOSURE LIMITS	U.S. OSHA PEL: 15mg/m^3 as particulate not otherwise regulated. Permissible exposures may vary from juresdiction to juresdiction. Consult local authorities for acceptable exposure limits in your area.

Section IX. Physical and Chemical Properties

PHYSICAL STATE AND APPEARANCE	Solid prills		
MOLECULAR WEIGHT	Not available.	**COLOR**	White.
pH (10% SOLN/WATER)	6 [Acidic.]	**ODOR**	Odorless.
BOILING POINT	Decomposes.	**ODOR THRESHOLD**	Not available.
MELTING POINT	170°C (338°F)	**TASTE**	Disagreeable. Acrid. (Strong.)
CRITICAL TEMPERATURE	Not available.	**VOLATILITY**	0% (v/v). 0% (w/w).
SPECIFIC GRAVITY g/cc	0.92 (Water = 1)	**SOLUBILITY**	Easily soluble in cold water, hot water. Soluble in acetone. Partially soluble in methanol.
BULK DENSITY kg/m^3 ; lbs/ft^3	Loose: 913; 57.7	**DISPERSION PROPERTIES**	See solubility in water, methanol, acetone.
VAPOR PRESSURE	0 mm of Hg (@ 20°C)	**WATER/OIL DIST. COEFF.**	Not available.
VAPOR DENSITY	Not available.		

Section X. Stability and Reactivity Data

STABILITY	The product is stable.
INSTABILITY TEMPERATURE	Not available.
CONDITIONS OF INSTABILITY	No additional information.
INCOMPATABILITY WITH VARIOUS SUBSTANCES	Reactive with combustible materials. Slightly reactive to reactive with reducing agents, organic materials, metals, moisture. Very slightly to slightly reactive with alkalis. Non-reactive with acids.
CORROSIVITY	Slightly corrosive to aluminum, zinc, and copper. Non-corrosive to steel and stainless steel (304 or 316).
SPECIAL REMARKS ON REACTIVITY	Absorbs moisture from the air. Incompatible with magnesium, zinc, sodium, potassium, and other finely powdered metals. May explode by detonation, heat or shock.
SPECIAL REMARKS ON CORROSIVITY	Avoid contact with moisture. Slow hydrolysis will produce acids which may slowly corrode metals. Contact your sales representative or a metallurgical specialist to ensure compatability with system equipment.

Continued on Next Page

Section XI. Toxicological Information

SIGNIFICANT ROUTES OF EXPOSURE	Ingestion. Inhalation.
TOXICITY TO ANIMALS	See Section II.
SPECIAL REMARKS ON TOXICITY TO ANIMALS	Toxic to livestock, wildlife, and domestic animals if directly ingested. Ensure that all spillage is cleaned up and that top dressing on pasture lands is applied uniformly. Allow 2 - 4 days to pass after application before returning livestock to pasture. The product itself and its products of degradation are not harmful under normal conditions of careful and responsible use.
OTHER EFFECTS ON HUMANS	Recent studies undertaken by the U.S. Government using Canadian and American databases have determined that ammonium nitrate fertilizer does not demonstrate any risk of gastrointestinal cancer.
SPECIAL REMARKS ON CHRONIC EFFECTS ON HUMANS	Exposure can cause headache, stomach pains, vomiting and diarrhea. Produces methemoglobin which reduces oxygen supply in the circulating blood. Although predominantly affecting infants, nitrate induced methemoglobinemia has also been documented in adults.
SPECIAL REMARKS ON OTHER EFFECTS ON HUMANS	No additional remark.

Section XII. Ecological Information

ECOTOXICITY	Non-persistent. Non-cumulative when applied using normal agricultural practises. Low toxicity for humans or animals under normal conditions of use. May be harmful to livestock and wildlife if ingested. Clean up all spilled material, especially where bulk fertilizer loading of equipment occurs to prevent animal exposure. Aquatic/Marine Toxicity: Will release ammonium ions. Ammonia is a toxic hazard to fish. Avoid spills or release to watercourses. Will disperse with current. Release to watercourses may cause effects down stream from the point of release. U.S. D.O.T.: This material NOT listed as a Marine pollutant.
BOD and COD	Not available.
PRODUCTS OF DEGRADATION	Not applicable.
TOXICITY OF THE PRODUCTS OF DEGRADATION	The product itself and its products of degradation are not harmful under normal conditions of use. Avoid spills or releases to watercourses.
SPECIAL REMARKS ON THE PRODUCTS OF DEGRADATION	Product will promote algae growth which may degrade water quality and taste. Notify downstream water users. Nitrate in potable drinking water should be maintained below 10mg/L. Will dissolve and disperse in water.

Section XIII. Disposal Considerations

WASTE DISPOSAL OR RECYCLING	Recycle to process, if possible. Recover and place material in a suitable container for intended use or disposal. Ensure disposal complies with government requirements and local regulations.

Section XIV. Transport Information

DOT / TDG CLASSIFICATION	TDG/DOT CLASS 5.1: Oxidizing substance.
PIN and Shipping Name	Proper shipping name: Ammonium nitrate PIN #: UN1942
SPECIAL PROVISIONS FOR TRANSPORT	U.S. DOT: A1, A29, IB8, IP3

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DOT (U.S.A) (Pictograms)

Section XV. Other Regulatory Information and Pictograms

OTHER REGULATIONS

U.S. Allowable Tolerances (FIFRA Requirements):
1. Ammonium nitrate is exempted from the requirement of a tolerance when used as a desiccant or defoliant in the production of cottonseed, grain sorghum, peppers, potatoes, sweet potatoes. 40 CFR 180.1018 (7/1/91)
2. Ammonium nitrate is exempted from the requirement of a tolerance when used as an adjuvant/intensifier for herbicides in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only. 40 CFR 180.1001(d) (7/1/91)

FDA Requirements:
1. Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (d)(1)(ii) of this section, meet the standards of chemical quality and shall not contain nitrate, as nitrogen, in excess of 10.0 mg/l. /Nitrate, as nitrogen. 21 CFR 103.35 (4/1/91)

TSCA - Sect. 8(b) Inventory: XU

California - Air Bill 2588 (Air Toxics Hot Spots) Appendix A-I: 6/91; ADOA 100.0 lbs/yr
California - Toxic Air Contaminant List Category III (AB 1807, AB 2728)
Massachusetts RTK List - Present
NJ Department of Health RTK List: sn 0106
NJ Special Hazardous Substances: (reactive - third degree)
Pennsylvania RTK List: environmental hazard
Rhode Island Hazardous Substance List - Present

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA): This product or its ingredients is on the Domestic Substances List (DSL), and acceptable for use under the provisions of CEPA.
Canada - Domestic Substances List - Present
Canada - WHMIS Classification of Substances: C; D2B
EINECS Inventory: 229-347-8

Japan - Existing and New Chemical Substances Inventory: 1-395
Korea - Existing and Evaluated Chemical Substances Inventory: KE-01715
Taiwan - Dangerous and Toxic Materials List: Dangerous material - Oxidizer
CERCLA/SUPERFUND, 40 CFR 117, 302: This product contains no Reportable Quantity (RQ) Substances.

SARA HAZARD CATEGORY: This product has been revised according to the EPA "Hazard Categories" promulgated under Sections 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to meet the following category(ies):
Immediate Health, Fire, Reactive
The following product is listed in SARA Section 313 (40 CFR Part 372):
Ammonium nitrate, CAS # 6484-52-2 (if in solution and dissociated). Refer to EPA guidance document 745-R-00-006 for information on TRI reporting for nitrates.

This product is not considered as a priority pollutant as regulated under the Clean Water Act.
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

OTHER CLASSIFICATIONS

HCS (U.S.A.)	HCS CLASS: Oxidizer.
DSCL (EEC)	R2- Risk of explosion by shock, friction, fire or other sources of ignition. R8- Contact with combustible material may cause fire. R9- Explosive when mixed with combustible material.

National Fire Protection Association (U.S.A.)

Hazards presented under acute emergency conditions only:

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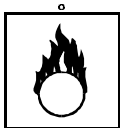
TDG (Pictograms - Canada)

DSCL (Europe) (Pictograms)



ADR (Europe) (Pictograms)

Section XVI. Other Information

REFERENCES

-Transportation of Dangerous Goods Act and Clear Language Regulations.
-Canada Gazette Part II, Vol. 122, No. 2 Registration SOR/88-64 31 December, 1987 Hazardous Products Act "Ingredient Disclosure List".
-Domestic Substances List, Canadian Environmental Protection Act.
-Canadian Centre for Occupational Health and Safety Infodisk Series
-29 CFR Part 1910
-33 CFR Parts 151, 153, 154, 156
-40 CFR Parts 1-799
-46 CFR Part 153
-49 CFR Parts 1-199
-American Conference of Governmental Industrial Hygienists, Threshold Limit Values for Chemical Substances, 2002.
-Fire Protection Guide to Hazardous Materials, (NFPA49, 325M, 491M, and 704), National Fire Protection Association, 10th Ed, 1991
-Corrosion Data Survey, Sixth Edition, 1985, National Association of Corrosion Engineers
-TOMES® System: Heitland G & Hurlbut KM (Eds) (electronic version): MICROMEDEX, Greenwood Village, Colorado, USA. Available at: http://csi.micromedex.com (2002). The TOMES® System includes MEDITEXT® Medical Management; HAZARDTEXT® Hazard Management; INFOTEXT® Documents; ERG2000 Emergency Response Guidebook Documents; REPROTEXT®: Heitland G & Hurlbut KM (Eds); CHRIS Hazardous Chemical Data: U.S. Department of Transportation, U.S. Coast Guard, Washington, D.C. (2002); HSDB: Hazardous Substances Data Bank. National Library of Medicine, Bethesda, Maryland (2002); IRIS: Integrated Risk Information System. U.S. Environmental Protection Agency, Washington, D.C. (2002); NIOSH: Pocket Guide to Chemical Hazards. National Institute for Occupational Safety and Health, Cincinnati, Ohio (2002); OHM/TADS: Oil and Hazardous Materials Technical Assistance Data System. U.S. Environmental Protection Agency, Washington, D.C. (2002); REPROTOX®: Scialli A.R. Georgetown University Medical Center and Reproductive Toxicology Center, Columbia Hospital for Women Medical Center, Washington, D.C. (2002); RTECS®: Registry of Toxic Effects of Chemical Substances. National Institute for Occupational Safety and Health, Cincinnati, Ohio (2002); and SHEPARDS: Shepard T.H.: Shepard's Catalog of Teratogenic Agents (2002).
-The Fertilizer Institute Product Testing Program Results, March 2003

OTHER SPECIAL CONSIDERATIONS

Not applicable.

FOR FURTHER SAFETY, HEALTH, OR ENVIRONMENTAL INFORMATION ON THIS PRODUCT, CONTACT

AGRIUM
Environment, Health and Safety Department
Telephone (403) 225-7380 or Fax (403) 225-7608

NOTICE TO READER

MATERIAL SAFETY DATA SHEET FOR ELECTRODE PREP PAD
PDI - PROFESSIONAL DISPOSABLES INTERNATIONAL
HEALTHCARE DIVISION OF
NICE-PAK PRODUCTS, INC
TWO NICE-PAK PARK
ORANGEBURG NY 10962-1376
845-365-1700
REVISION DATE: 7/00

I-PRODUCT IDENTIFICATION
PRODUCT/TRADE NAME: ELECTRODE SKIN PREP PAD - B59800
HAZARD RATING (NFPA)
HEALTH: 1
FLAMMABILITY: 3
REACTIVITY: 0
SPECIFIC: NONE
EMERGENCY OR INFORMATION TELEPHONE NO: 845-365-1700 (M-F DAYTIME) AT OTHER TIMES, CONTACT THE LOCAL POISON CONTROL CENTER

CHEMICAL NAME: ISOPROPYL ALCOHOL

II-HAZARDOUS INGREDIENTS PER 29 CFR 1910.1200

Hazardous Ingredients	%	ACGIH TLV	CAS NUMBER
2-PROPANOL	70	400 ppm	67-63-0

III-PHYSICAL/CHEMICAL CHARACTERISTICS
COLOR/ODOR/APPEARANCE: TOWELETTE/PAD SATURATED WITH CLEAR LIQUID WITH LIGHT BROWN PARTICLES AND ALCOHOL ODOR
BOILING POINT: N/A
FLASH POINT: 78°F
VAPOR DENSITY: N/A
EVAPORATION RATE: N/A
SOLUBILITY IN WATER: COMPLETE
SPECIFIC GRAVITY (H_2O = 1):N/A

IV-FIRE & EXPLOSION HAZARD DATA
FLASH POINT(Method Used): 78°F TAG CLOSED CUP: LEL:2.0 UEL:12.0
EXTINGUISHING MEDIA: DRY CHEMICAL OR ALCOHOL TYPE FOAM, CARBON DIOXIDE
SPECIAL FIRE FIGHTING PROCEDURES: HANDLE AS FLAMMABLE LIQUID. USE RESPIRATORY PROTECTION FOR FIRE FIGHTING PERSONNEL
UNUSUAL FIRE AND EXPLOSION HAZARDS: CLASS 3 FLAMMABILITY

V-REACTIVITY DATA
STABILITY: STABLE
CONDITIONS TO AVOID: NONE
INCOMPATIBILITY: NONE
HAZARDOUS DECOMPOSITION OR BYPRODUCTS: NONE
POLYMERIZATION: WILL NOT OCCUR
CONDITIONS TO AVOID: NONE

VI-HEALTH HAZARD DATA
EFFECTS OF OVER EXPOSURE:
SKIN: IF RASH APPEARS, DISCONTINUE USE
EYES: WILL CAUSE EYE STING IF SPLASHED
INHALATION: NONE
INGESTION: NOT A NORMAL ROUTE OF ENTRY
EMERGENCY AND FIRST AID PROCEDURES:
SKIN CONTACT: DISCONTINUE USE IF RASH OR IRRITATION OCCURS
EYE CONTACT: FLUSH WITH COLD WATER FOR 15 MINUTES
INHALATION: REMOVE TO FRESH AIR
INGESTION: INDUCE VOMITING. CALL PHYSICIAN
TARGET ORGANS: N/A

VII-SPILL AND DISPOSAL PROCEDURE
SPILL CONTROL: ELIMINATE ALL SOURCES OF IGNITION
WASTE DISPOSAL METHOD: FLUSH SPILLS WITH WATER. HANDLE AS FLAMMABLE LIQUID. FOLLOW LOCAL, STATE AND FEDERAL REGULATIONS.
HANDLING AND STORAGE: STORE AWAY FROM HEAT AND SOURCES OF IGNITION

VIII-CONTROL MEASURES/PROTECTION
RESPIRATION: USE IF PERMISSABLE EXPOSURE LEVEL IS EXCEEDED WHEN HANDLING BULK LIQUID
VENTILATION: RECOMMENDED
PROTECTIVE GLOVES: NONE REQUIRED
EYE PROTECTION: ONLY IF SPLASHING IS EXPECTED
HYGIENIC PRACTICES: GOOD HOUSEKEEPING PRACTICES SHOULD BE FOLLOWED
OTHER: DON'T ALLOW LARGE QUANTITIES OF WASTE TO ACCUMULATE

IX-TRANSPORT/SHIPPING

DOT SHIPPING NAME: CONSUMER COMMODITY
TECHNICAL SHIPPING NAME: N/A
DOT SHIPPING CLASSIFICATION: "ORM-D"
DOT ID NO.: N/A
DOT LABEL REQUIREMENTS: N/A
UN/NA NUMBER REGULATIONS: N/A
REPORTABLE QUANTITY: N/A

X-DISCLAIMER
THE INFORMATION FURNISHED HEREIN IS BELIEVED TO BE ACCURATE AND REPRESENTS THE BEST DATA CURRENTLY AVAILABLE TO US. NO WARRANTY, EXPRESSED OR IMPLIED IS MADE AND NICE-PAK PRODUCTS, INC. ASSUMES NO LEGAL RESPONSIBILITY OR LIABILITY RESULTING FROM ITS USE.

Professional Disposables International
Two Nice-Pak Park, Orangeburg, NY 10962
845-365-1700 / Email: info@pdipdi.com
Canada 800-263-7067 / Europe 441-352-763-511

MATERIAL SAFETY DATA SHEET

1. Identification Of The Material And Supplier

Product Name:	Burnaid Sachets Burnaid Dressings Burnaid Tubes. Burnaid Spray Gel and Squeeze Bottle.
Other Names:	None.
Recommended Use:	First aid treatment for burns.
Supplier Name:	Rye Pharmaceuticals Pty Ltd.
Address:	Level 2, 52 Gibbes Street Chatswood 2067 NSW Sydney Australia.
Telephone:	+ 61 (0)2 9417 1922
Fax:	+ 61 (0)2 9417 0201

Emergency Contact Poisions Information Centre 24 Hours: (Australia) 13 11 26

A first aid burn gel for use on burns. Relieves pain, cools and soothes, provides a moist re-hydrating barrier and helps prevent secondary infection. Available as a gel and gel impregnated open cell foam dressings

Dressings

- An open cell polyester foam impregnated with white/off white to slightly clear hydrogel with a tea tree oil odour contained in a plastic/foil/plastic laminate pouch

Gel Tubes/Sachets/Bottles

- A white/off white to slightly clear hydrogel with a tea tree oil odour contained in a plastic/foil/plastic laminate sachet, tube or bottle.

2. Hazards Identification

Hazard Classififcation:	Classified as Non-hazardous according to criteria of NOHSC
Hazard Category:	None.
Risk Phrases:	None.
Safety Phrases:	None.

Material Details

CAS No.	None
NIOSH No.	None
UN No.	None
Dangerous G. Class	None
Packaging Group	None
IMO Class	None
Poison Schedule	None
HAZCHEM	None
Sub Risk	None
EPG	None
IMDG Page	None
Label	No class assigned
Shipping Name	**BURNAID**

3. Composition / Information on Ingredients

The Ingredients below are **NOT** considered either hazardous, dangerous goods or poisions at the percentage present according to the criteria of NOHSC

Single Use Dressings, Sachet & Gel Spray/Bottle

- Melaleuca Oil 1%
- Thickeners
- Emulsifiers and Surfactant
- Purified Water

Tube Gel

- Melaleuca Oil - 4%
- Thickeners
- Emulsifiers Surfactant
- Preservative
- Purified Water - 90%

Sterility

Single Use Sachets, Dressings and Gel Spray are sterilised by Gamma Irradiation – Minimum dosage of 25kygs

STERILE R

4. First Aid measures

- **Swallowed** - If swallowed, give a glass of water.
- **Eye Contact -** hold eye open and flush out the eye - especially under the eyelids with fresh water or saline solution. Seek medical attention if any irritation continues.
- **Skin** - If irritation occurs, discontinue use and wash off with fresh water.
- **Inhalation** - Not applicable.
- **Other** - Melaleuca Oil is generally considered a non-irritant in inert formula's below 10% concentration, and considered non-toxic at levels of less than 25% concentration. Industry studies indicate allergic reaction to products containing less than 10% Melaleuca Oil is extremely rare, but when reported usually involves some redness and stinging of the skin.

Toxicity	LD50>10g/kg
Skin Sensitisation	Non irritant
Skin Irritation	Non irritant
Eye Irritation	1 Draize Scale - very mild irritant

Treat symptomatically. Refer to individual constituents

5. Fire Fighting Methods

Fire Explosion – None - this product is non-combustible.

Non Flammable however the packaging may burn & emit fumes.

6. Accidental Release measures

Spills or Leakages – Contain the spill and wipe up then wash down area with water or absorb with sponge. Place in waste disposal.

7. Safe Handling and Storage

Protective Equipment – None required.

Storage and Transport - Store in packaging provided and in a cool dry place. Avoid extreme temperatures and sharp objects that may pierce the packaging. Do not use if the packaging is damaged. Can be refrigerated but do not freeze.

Shipping Name – None.

8. Exposure Controls / Personal Protection

Exposure limits – None Known.

Engineering Controls – None.

No special equipment is required for normal handing.

9. Physical And Chemical Properties

Molecular Weight:	Not applicable
Boiling Range:	Not applicable
Melting Range:	Not applicable
Specific Gravity:	0.98 to 1.02
Water Solubility:	Miscible
Evaporation Rate:	Not available
State:	Gel
Vapour Pressure:	Not available
Volatile Component (%Vol):	Not available
Relative Vapour Density:	Not available
Flash Point:	Not applicable
Lower Explosive Limit (%):	Not applicable
Upper Explosive Limit (%):	Not applicable
Auto ignition Temp©:	Not applicable
Decomposition Temp ©:	Not available

10. Stability And Reactivity

Hazardous Reactions – None known.

11. Toxicological Information.

Acute Effects:

SWALLOWED

Considered an unlikely route of entry. It is doubtful whether enough could be ingested to cause any irritation to the gastro-intestinal tract, or cause any pain or vomiting. Pure Melaleuca Oil is considered toxic. However formulation under 25% is considered non-toxic. Oral Toxicity Testing indicated the LD50 to be greater than 10g/kg, indicating very low potential irritancy.

EYE

Considered a possible mild irritant to the eye and may cause some smarting and redness. Acute Eye Irritation Testing using the Draize procedure indicated a very mild eye irritant.

SKIN

Generally considered a non-irritant. Prolonged exposure may cause some mild irritation and redness in a very small number of people. In rare cases skin contact may cause some irritation during use. Acute Dermal Irritation and Skin Sensitisation Testing in accordance with Draize procedure indicated a non-irritant and non-sensitising.

INHALATION

No hazard as product is non-volatile.

CHRONIC

Prolonged contact may cause slight irritation or redness for a small number of people. Pure Melaleuca Oil is considered a mild irritant, however percentages under 10% are usually considered non-irritants.

Australia Poisons Information Centre

24 Hour Service	13 11 26
Police or Fire Brigade	000

New Zealand Poisons Information Centre

Dunedin	03 479 1200 (Normal Hours) 03 479 0999 (Emergency)

American Poison Help Line (24 Hours) 1-800-222-1222

12. Ecological Information

Environmental Protection – Generally considered non-hazardous to the environment.

13. Disposal Considerations

Disposal method – The product is suitable for disposal into landfill.

14. Transport Information

Road And Rail Transport – Product is not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG) for transport by Road and Rail.

Marine Transport - Product is not classified as Dangerous Goods by the criteria of the International Maritime Dangerous Goods Code (IMDG) for transport by Sea.

Air Transport - Product is not classified as Dangerous Goods by the criteria of the International Air Transport Association (IATA) for transport by Air.

15. Regulatory Information

TGA Status – ARTG Identifier 179506
ARTG Start Date – 27/01/2011
Product Category – Medical Device included in Class 11a.

Intended Purpose – a Sterile Wound Dressing used to provide First aid Treatment for burns.

16. Other Information

MSDS Issue Date: February 2011
MSDS Reviewed Date: May 2014

Reasons for review: Regular check of currency of information

The information contained in this data sheet is accurate to the best of our knowledge as of the date issued. It is the users obligation to assess that the product is suitable for the purpose chosen, and that it is used in accordance with the instructions.

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, REACH, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I *What is the material and what do I need to know in an emergency?*

1. SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

TRADE NAME/MATERIAL NAME: Triple Antibiotic Ointment

DESCRIPTION: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Ointment
NDC #: 0168-0012-09; 0168-0012-31; 0168-0012-35
CHEMICAL NAME (for active ingredients):

Bacitracin Zinc: (2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-{[(1R,2R,3S,4R,6S)-4,6-diamino-2-{[(2S,3R,4S,5R)-4-{[(2R,3R,4R,5S,6S)-3-amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy}-3- amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy}-3-hydroxy-5-(hydroxymethyl)oxolan-2-yl]oxy}-3-hydroxycyclohexyl]oxy}oxane-3-hydroxycyclohexyl]oxy}oxane-3,4-diol;

Neomycin Sulfate: 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine;

Polymixin B Sulfate: (4*R*)-4-[(2*S*)-2-({2-[(1*S*)-1-amino-2-methylbutyl]- 4,5-dihydro-1,3-thiazol-5-yl}formamido)-4-methylpentanamido]-4-{[(1*S*)- 1-{[(3*S*,6*R*,9*S*,12*R*, 15*S*,18*R*,21*S*)- 18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)- 6-(carboxymethyl)-9-(1*H*-imidazol)

CHEMICAL FAMILY: Bacitracin Zinc: Cyclic Polypeptide; Neomycin Sulfate and Polymixin B Sulfate: Aminoglycosides
HOW SUPPLIED: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Topical Ointment
FORMULA (for active ingredient): Bacitracin Zinc: $C_{66}H_{103}N_{17}O_{16}SZn$; Neomycin Sulfate: $C_{23}H_{46}N_6O_{13}\bullet 3H_2O_4S$; Polymyxin B Sulfate: $C_{43}H_{82}N_{16}O_{12}\bullet H_2O_4S$
RELEVANT USE of the SUBSTANCE: Pharmaceutical for Human Use
USES ADVISED AGAINST Other than Relevant Use
SUPPLIER/MANUFACTURER'S NAME: **FOUGERA PHARMACEUTICALS INC.**
ADDRESS: 60 Baylis Road
Melville, NY 11747
BUSINESS PHONE/GENERAL SDS INFORMATION: 1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico): CHEMTEL: (U.S, Canada, Int'l) 1(813) 676-1670 (24 hrs)

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: ***Product Description:*** This product is a pale yellow ointment with a petroleum jelly odor. ***Health Hazards:*** May be harmful if swallowed. Prolonged skin contact may be irritating. Individuals who have had allergic reactions to aminoglycosides may experience allergic reactions to this product, including skin and respiratory sensitization and allergic reactions. Therapeutic use of this product may cause adverse symptoms on the neurological system, ears, liver and kidneys. Due to the Neomycin Sulfate component, this product may cause harm to the fetus during pregnancy. ***Flammability Hazards:*** If heated to high temperatures for a prolonged period, this product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects, however, all release to the environment should be avoided. One active ingredient may cause acute and chronic toxicity to aquatic organisms. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENTS				
Bacitracin Zinc L-isoleucinamide, N-[[2-(1-amino-2-methylbutyl)-4,5-dihydro-4-thiazolyl]carbonyl]-L-leucyl-D-α-glutamyl-N-[(3S,6R,9S,12R,15S,18R,21S)-3-(2-amino-2-oxoethyl)-18-(3-aminopropyl)-6-(carboxymethyl)-9-(1H-imidazol-5-ylmethyl)-15-(1-methylpropyl)-2,5,8,11,14,17,20-heptaoxo-12-(phenylmethyl)-1,4,7,10,13,16,19-heptaazacyclopentacos-21-yl]-, zinc salt (1:1)	1405-89-6	215-787-8	500 Units	SELF-CLASSIFICATION EU 67/548 Classification: Irritant, Dangerous for the Environment Risk Phrase Codes: R43, R53/53 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Skin Sensitization Cat. 1B, Aquatic Acute Toxicity Cat. 3, Aquatic Chronic Toxicity Cat. 3 Hazard Codes: H317, H402, H412 Hazard Symbol/Pictogram: GHS08

See Section 16 for full classification information of product and components.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENTS (continued)				
Neomycin Sulfate 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine	1405-10-3	215-773-1	0.4%	SELF-CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant Risk Phrase Codes: R63, R42/43, R36/38, R33 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Reproductive Toxicity Cat. 2, Skin Sensitization Cat. 1A, Respiratory Sensitization Cat. 1B, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, STOT RE Cat. 2 Hazard Codes: H361d, H317, H334, H315, H319, H373 Hazard Symbol/Pictogram: GHS07, GHS08
Polymixin B Sulfate (4*R*)-4-[(2*S*)-2-({2-[(1*S*)-1-amino-2-methylbutyl]-4,5-dihydro-1,3-thiazol-5-yl}formamido)-4-methylpentanamido]-4-{[(1*S*)- 1-{[(3*S*,6*R*,9*S*,12*R*,15*S*,18*R*,21*S*)- 18-(3-aminopropyl)-12-benzyl-15-(butan-2-yl)-3-(carbamoylmethyl)- 6-(carboxymethyl)-9-(1*H*-imidazol)	1405-20-5	215-774-7	10,000 Units	SELF-CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrase Codes: R22, H36/38 Hazard Symbols: Xn/Xi GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Irritation Cat. 2A Hazard Codes: H302, H315, H319 Hazard Symbol/Pictogram: GHS07
EXCIPIENTS				
White Petrolatum	8009-03-8	232-373-2	Proprietary	EU 67/548 Classification: Carcinogenic Cat. 2 Risk Phrase Codes: R45 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 1B Hazard Codes: H350 Hazard Symbol/Pictogram: GHS08

See Section 16 for full classification information of product and components.

PART II *What should I do if a hazardous situation occurs?*

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

Skin Exposure: If adverse skin effects occur, discontinue use. Seek medical attention.

Eye Exposure: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Inhalation: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing liver and kidney conditions and hearing problems and may be aggravated by exposure to this product. Dehydration increases the toxicity of Neomycin Sulfate. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to aminoglycosides or the components, and other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. No specific antidote is known. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available. ***AUTOIGNITION TEMPERATURE:*** Not available.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

5. FIRE-FIGHTING MEASURES (Continued)

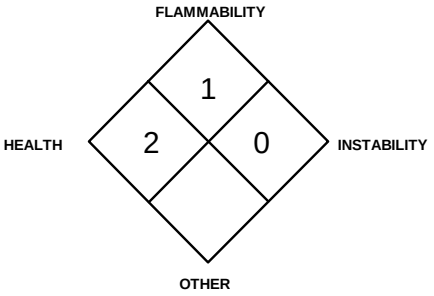
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: If heated to high temperatures for a prolonged period this product can ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides).

Explosion Sensitivity to Mechanical Impact or Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.

PROTECTIVE EQUIPMENT:

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: The product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat.

7. HANDLING and USE (Continued)

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT (continued): Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls*:* Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	*CAS #*	*EXPOSURE LIMITS IN AIR*							
		ACGIH-TLVs		*OSHA-PELs*		*NIOSH-RELs*		*NIOSH*	*OTHER*
		TWA mg/m³	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*IDLH mg/m³*	*mg/m³*
Bacitracin Zinc	1405-89-6	NE	NE	NE	NE	NE	NE	NE	NE
Neomycin Sulfate	1405-10-3	NE	NE	NE	NE	NE	NE	NE	NE
Polymixin B Sulfate	1405-20-5	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established See Section 16 for Definitions of Terms Used.

International Occupational Exposure Limits: No additional international exposure limits are available for components. Exposure limits are added or changed and should be check periodically.

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Ointment.
COLOR: Pale yellow.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Petroleum jelly odor.
ODOR THRESHOLD: Not established.
BOILING POINT: 200°C (392°F)
MELTING POINT: 58°C (136°F)
EVAPORATION RATE (nBuAc = 1): Not established.
pH: Not established.
VAPOR PRESSURE (air = 1): < 1 mmHg
SPECIFIC GRAVITY @ 60°C (water = 1): 0.85
SOLUBILITY IN WATER: Insoluble.
OTHER SOLUBILITIES: Not known.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon, nitrogen, zinc and sulfur oxides). ***Hydrolysis:*** None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

10. STABILITY and REACTIVITY (Continued)

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Although unlikely, due to high viscosity of the product, inhalation of mists or sprays of this product, especially in a poorly ventilated space, may cause irritation, coughing, and sneezing.

Contact with Skin or Eyes: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals. Eye contact can cause temporary blurred vision and irritation.

Skin Absorption: Neomycin and Polymyxin B Sulfates can be absorbed through open wounds, burns, and granulating surfaces. Absorption can be significant and can adversely affect the kidneys and destroy fibers of the acoustic nerve and cause permanent bilateral deafness. When absorbed, Neomycin and Polymyxin B are nephrotoxic antibiotics (can cause damage to the liver), and the nephrotoxic potentials are additive.

Ingestion: Ingestion is not a significant route of occupational exposure. Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, diarrhea and inflammation of the small intestine and the colon. Although ingestion may cause severe allergic reactions, reactions are rare. Neuromuscular blockage and respiratory paralysis have been reported following the oral use of Neomycin. Chronic ingestion caused by poor hygiene practices may cause weight loss, diarrhea, excess fat in the stools, excessive discharge of nitrogenous substances in the feces or urine, difficulty digesting dairy products, intestinal crypt-cell necrosis, kidney damage, hearing loss, and hair loss.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms of intramuscular injection of Bacitracin Zinc may include loss of appetite, nausea, vomiting, diarrhea, rectal itching and burning, skin rashes, pain, hives, fever, bone marrow toxicities, blood dyscrasias, eosinophilia, kidney damage, and anaphylactoid reactions. Reaction may be life-threatening in certain individuals.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, damage to the kidneys, liver or renal damage, ototoxicity (damage to hearing) and neuromuscular blockage have been reported. Hypersensitivity to aminoglycosides may cause rash. Ingestion can cause serious allergic reactions in susceptible individuals. Allergic reaction by inhalation may be possible. Increased liver toxicity has been reported following concurrent administration of aminoglycosides and cephalosporins. Acute muscular paralysis and breathing disorders due to this can occur with aminoglycoside drugs. Can cause fetal harm. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue if contact is prolonged.

SENSITIZATION OF PRODUCT: Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Bacitracin is considered to be one of the most prevalent allergens. Rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: Ingestion may be harmful. Eye contact may cause irritation.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. May cause fetal harm. Chronic exposure to this material may cause adverse effects as described under 'General Toxicity Information'.

TARGET ORGANS:

Acute: *Occupational Exposure:* Skin, eyes. *Therapeutic Doses:* Skin.

Chronic: *Occupational Exposure:* Skin. *Therapeutic Doses:* Skin, other effects described under 'Other Potential Health Effects'.

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA: Only toxicity data available for the active component of this product are presented in this SDS. Additional data are available for the excipient components of this product, but are not presented; Contact Fougera for more information.

NEOMYCIN SULFATE:

Standard Draize Test (Skin-Human) 6 mg/3 days-intermittent: Mild
Standard Draize Test (Skin-Human) 0.2%: Severe
TDLo (Oral-Human) 12,600 mg/kg/7 days: Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions, anorexia (human)
LD_{50} (Oral-Mouse) > 8 gm(base)/kg
LD_{50} (Subcutaneous-Rat) 200 mg/kg
LD_{50} (Subcutaneous-Mouse) 190 mg/kg
LD_{50} (Intraperitoneal-Mouse) 305 mg/kg
LD_{50} (Intravenous-Mouse) 17,400 µg/kg
LD_{50} (Intramuscular-Mouse) 142 mg/kg
LD_{50} (Intramuscular-Guinea Pig) > 250 mg/kg: Sense Organs and Special Senses (Ear): change in acuity
LD_{50} (Intracerebral-Mouse) 32 mg/kg
TDLo (Subcutaneous-Rat) 280 mg/kg/7 days-intermittent: Kidney/Ureter/Bladder: changes in bladder weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
TDLo (Subcutaneous-Mouse) 560 mg/kg/7 days-intermittent: Gastrointestinal: other changes; Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes
TDLo (Intravenous-Rat) 15 mg/kg: Behavioral: alteration of classical conditioning
TDLo (Intraspinal-Rat) 36.88 µg/kg: Behavioral: analgesia
TDLo (Intracerebral-Rat) 714.3 µg/kg: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Neurotransmitters or modulators (putative): catecholamine levels in CNS

NEOMYCIN SULFATE (continued):

TDLo (Intramuscular-Monkey) 500 mg/kg/5 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Kidney/Ureter/Bladder: other changes in urine composition
TDLo (Intramuscular-Cat) 5050 mg/kg/14 weeks-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis), interstitial nephritis; Related to Chronic Data: death
TDLo (Intramuscular-Guinea Pig) 2 gm/kg/8 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Related to Chronic Data: death

POLYMIXIN B SULFATE:

Standard Draize Test (Skin-Child) 5%: Moderate
LD_{50} (Oral-Mouse) 790 mg(base)/kg
LD_{50} (Intraperitoneal-Mouse) 20,500 µg(base)/kg
LD_{50} (Subcutaneous-Mouse) 59,500 µg(base)/kg
LD_{50} (Subcutaneous-Guinea Pig) 58 mg/kg
LD_{50} (Intravenous-Mouse) 5400 µg(base)/kg
LDLo (Intravenous-Dog) 8 mg/kg
LDLo (Intracerebral-Dog) 320 µg/kg: Behavioral: coma
TDLo (Subcutaneous-Mouse) 284 mg/kg/9 days-intermittent: Behavioral: muscle weakness; Skin and Appendages: dermatitis, other (after systemic exposure); Skin and Appendages: hair
DNA Adduct (Bacteria-*Escherichia coli*) 50 mg/L
Mutation Test Systems-Not Otherwise Specified (Microorganism-Not Otherwise Specified) 25 mg/L
Mutation Test Systems-Not Otherwise Specified (Yeast-*Saccharomyces cerevisiae*) 5 mg/L

CARCINOGENIC INFORMATION: The following information is available for one of the active ingredients.

The effect of oral administration of Neomycin (100 and 200 µg/mL in drinking water) on colon tumors induced by azoxymethane (AOM) was studied in female F344 rats. 5-week-old rats were fed NIH-07 diet and given daily in drinking water 0, 100, and 200 µg neomycin/ml (0, 100, and 200 ppm). At 7 weeks of age, all animals except vehicle-treated groups received weekly sc injections of 8 mg AOM/kg bw for 8 weeks. The AOM- or vehicle-treated groups were necropsied 30 weeks after the last injection of AOM. The combined incidence of adenomas and adenocarcinomas of the colon did not differ significantly among the 3 groups. The animals in the groups given 100 and 200 µg neomycin had a higher incidence of colon adenocarcinomas than did those in the control group. Colonic and cecal bacterial beta-glucuronidase activity was significantly lower in the group given 200 µg Neomycin than it was in the control group. The excretion of fecal cholesterol, total bile acids, and deoxycholic acid was increased significantly in animals given 100 and 200 µg Neomycin as compared to animals given no Neomycin. These results suggest that long-term oral administration of neomycin increases the incidence of colon adenocarcinomas.

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of in pregnant women. This product has not been rated by the U.S. FDA for Pregnancy Risk Category. The following information is available for the Neomycin Sulfate active ingredient.

Mutagenicity: Studies in humans have not been performed with the aminoglycosides, including Neomycin Sulfate to determine potential mutagenic effect. Treatment of cultured human lymphocytes *in vitro* with Neomycin increased the frequency of chromosome aberrations at the highest concentrations (80 µg/mL) tested; however, the effects of Neomycin on mutagenesis in humans are unknown. Long- term studies in animals to evaluate or mutagenic potential have not been conducted with Polymyxin B Sulfate.

Embryotoxicity/Teratogenicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received streptomycin (a related aminoglycoside) during pregnancy. Although serious side effects to the fetus or newborns have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists.

Reproductive Toxicity: No long-term animal studies have been performed with Neomycin Sulfate to evaluate impairment of fertility. It is not known whether neomycin is excreted in human milk, but it has been shown to be excreted in cow milk following a single intramuscular injection. Other aminoglycosides have been shown to be excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioconcentration.

ECOTOXICITY: No specific information is currently available on the effect of this product on plants or animals in the environment.

12. ECOLOGICAL INFORMATION (Continued)

ECOTOXICITY (continued): This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following data are available for one active component.

BACITRACIN ZINC:

LC_{50} (Trout) 96 hours = 74 mg/L

EC_{50} (Artemia sp. Brine shrimp) 48 hours = 18,500-25,700 µg/L (21.82 mg/L)

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Neomycin component is listed on the California Proposition 65 lists, when used in oral therapeutic use. Since this is a topical preparation, this listing does not apply to this product.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations.

15. REGULATORY INFORMATION (Continued)

UNITED STATES REGULATIONS (continued):

Other U.S. Federal Regulations (continued): Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: No component is on the CEPA Priorities Substances List.

Other Canadian Regulations: Not applicable.

Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** MAY HARMFUL IF ACCIDENTALLY INGESTED. PROLONGED THERAPEUTIC USE MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE ALLERGIC SKIN AND RESPIRATORY REACTIONS. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY. CONTAINS TRACE COMPOUND THAT MAY CAUSE ACUTE AND CHRONIC HARM TO AQUATIC ORGANISMS. Do not taste or swallow. Avoid contact with skin or clothing. Avoid breathing mists or sprays. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, call a physician immediately. Do NOT induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Bacitracin Zinc: This is a self-classification.
Classification: Skin Sensitization Category 1B, Aquatic Acute Toxicity Category 3, Aquatic Chronic Toxicity Category 3
Hazard Statements: H317: May cause an allergic skin reaction. H402: Harmful to aquatic life. H412: Harmful to aquatic life with long-lasting effects.

Neomycin Sulfate: This is a self-classification.
Classification: Reproductive Toxicity Category 2, Skin Sensitization Category 1A, Respiratory Sensitization Category 1B, Skin Irritation Category 2, Eye Irritation Category 2A, Specific Target Organ Toxicity Repeated Exposure Category 2
Hazard Statements: H361: Suspected of damaging fertility or the unborn child. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H373: May cause damage to the liver through prolonged or repeated exposure.

Polymixin B Sulfate: This is a self-classification.
Classification: Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Irritation Category 2A
Hazard Statements: H302: May be harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation.

White Petrolatum: The following is a Self-Classification.
Classification: Carcinogenic Category 1B
Hazard Statements: H350: May cause cancer.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Bacitracin Zinc: This is a self-classification.
Classification: Irritant, Dangerous for the Environment
Risk Phrases: R43: May cause sensitisation by skin contact. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Neomycin Sulfate: This is a self-classification.
Classification: Reproductive Toxicity Category 3, Harmful, Irritant
Risk Phrases: R63: Possible risk of harm to the unborn child. R42/43: May cause sensitisation by inhalation and skin contact. R36/38: Irritating to eyes and skin. R33: Danger of cumulative effects.

16. OTHER INFORMATION (Continued)

CLASSIFICATION FOR COMPONENTS (continued):

Full Text EU 67/548/EEC (continued):

Polymixin B Sulfate: This is a self-classification.

Classification: Harmful, Irritant

Risk Phrases: R22: May be harmful if swallowed. R36/38: Irritating to eyes and skin.

White Petrolatum: The following is a Self-Classification.

Classification: Carcinogenic Category 2

Risk Phrases: R45: May cause cancer.

All Other Components: No classification has been published or is applicable.

REVISION DETAILS: May 2015: Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

***PREPARED BY*:** CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

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DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. **3A:** Substances that have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but that are clearly mutagenic in vitro and structurally related to known in vivo mutagens. **4:** Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) **5:** Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A–C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH: Immediately Dangerous to Life and Health. This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL" is placed next to the PEL that was vacated by Court Order.

SKIN: Used when a there is a danger of cutaneous absorption.

STEL: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV: Threshold Limit Value. An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: **0** Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation*: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *Oral Toxicity LD_{50} Rat*: > 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: > 20 mg/L. **1:** Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation*: Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation*: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity LD_{50} Rat*: > 500–5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000–2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2–20 mg/L. **2** *Moderate Hazard*: Temporary or transitory injury may occur; prolonged exposure may affect the CNS.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **2 (continued):** *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation*: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity LD_{50} Rat*: > 50–500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200–1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5–2 mg/L. **3** Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1–50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20–200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05–0.5 mg/L. **4** Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation*: Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L.

FLAMMABILITY HAZARD: **0** Minimal Hazard: Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes. **1** Slight Hazard: Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.). **2** Moderate Hazard: Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. **3** Serious Hazard: Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°C (100°□F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IB and IC); Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air (e.g., dusts of combustible solids, mists or droplets of flammable liquids); and Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). **4** Severe Hazard: Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.) **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors.

DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC_{50} for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD_{50} for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued):**2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (**NFPA**). Flash Point: Minimum temperature at which a liquid gives off sufficient vapor to form an ignitable mixture with air near the surface of the liquid or within the test vessel used. Autoignition Temperature: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. UEL: Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. LD_{50}: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC_{50}: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m^3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. $\log K_{OW}$ or $\log K_{OC}$: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

This section explains the impact of various laws and regulations on the material. EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. WHMIS: Canadian Workplace Hazardous Materials Information System. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material's package label.

REVISION HISTORY

Date	**Changes**
November 16, 2015	Update CHEMTEL emergency phone number.
May 30, 2015	Change emergency telephone number to ChemTel.
May 23, 2015	Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.
September 30, 2014	New